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14. ABSTRACT

In Project 1, we are adapting and empirically evaluating a safety plan intervention targeted at suicidal military service members receiving care at the Walter Reed National Military Medical Center. Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. As of 9/24/2013, 93 participants have been enrolled. In Project 2, we are examining the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at high suicide risk at VA Emergency Departments (ED). Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit, as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post index ED visit. As of 9/24/2013, 332 participants have been enrolled across sites.

15. SUBJECT TERMS
Suicide Prevention, Safety Planning, Acute Care, Inpatient Treatment

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Introduction

The Army Suicide Event Reporting (ASER) and the Total Army Injury and Health Outcomes Database (TAIHOD) systems have indicated increasing rates of suicide among Active Army, Guard, and Reserve units over the last several years. Additionally, research has indicated that veterans are more than twice as likely to kill themselves as compared to the general population. There are limited evidence-based suicide prevention interventions that have been developed for military personnel and veterans who are experiencing suicide ideation or who have made a suicide attempt. The objective of the research described in this annual report is to adapt and evaluate a brief, readily accessible, and personalized intervention, safety planning, that aims to reduce suicide risk in military and veteran populations in three ways by: (1) evaluating suicide risk using a structured assessment measure; (2) enhancing suicide-related coping strategies; and (3) increasing acceptability and initiation of appropriate mental health and substance use treatments. This research is unique in that the intervention, safety planning, is being evaluated in both military and VA settings, with the aim of disseminating related educational materials to both military and VA patients and providers. The specific aims are to evaluate the efficacy of the safety planning intervention on suicide ideation, suicide-related coping, and attitudes toward help seeking for hospitalized military personnel at *high risk* for suicide and to evaluate the effectiveness of the safety planning intervention on suicide attempts, suicide ideation, attendance of outpatient mental health and substance abuse interventions, and suicide- related coping for veterans at high suicide risk in emergency department (ED) settings. Two separate, but related projects are being conducted to compare the study intervention with enhanced usual care conditions on suicide-related outcomes. In *Project 1*, the safety planning intervention has been adapted for military service members who are at high risk for suicide. A randomized controlled trial is being conducted to determine the efficacy of the safety planning intervention for hospitalized military personnel at the Walter Reed National Military Medical Center (formerly Walter Reed Army Medical Center). Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. In *Project 2*, a quasi-experimental design is being used to examine the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at *high risk* for suicide at VA ED. Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post the index ED visit. If the safety plan intervention is determined to be effective, then this intervention may be widely and quickly disseminated in the DoD and VA settings through publications and presentations using a variety of multi-media platforms. The ultimate goal of the safety plan dissemination initiative is to provide clinicians and other professionals who work with high risk military service members and veterans with a brief, easily administered intervention that is designed to mitigate suicide risk.

Body

During Year 4 of this project, our team has met all reporting guidelines for 19 regulatory agencies and obtained timely approvals on amendments as well as annual reviews. Recruitment of participants for SAFEMIL has progressed at the Walter Reed National Military Medical Center (WRNMMC) for Project 1 and as of September 24, 2013, a total of 93 participants have been recruited. In addition, we obtained IRB approvals to begin recruitment at a second military site, the Ft. Belvoir Community Hospital – however, given the request for a no cost extension and plans to end recruitment as of December 24, 2013 and a number of administrative delays in getting our staff members situated at Ft. Belvoir, we will not continue with plans to utilize this site for data collection. During Year 4, recruitment of participants for SAFEVET continued at the 4 control sites. One control site ended recruitment activities in December 2012, while the remaining 3 control sites ended recruitment activities on 8/24/2013. A total of 332 participants were recruited. Follow-ups for the study participants in both SAFEMIL and SAFEVET are in progress. The study PIs have been meeting at least once a week to discuss study objectives, methodology, timeline, and individual responsibilities in addition to problem solve implementation related challenges. Discussions are documented in weekly *Meeting Minutes*. Year 4 focused heavily on recruitment and follow-up for Project 1, control site recruitment and follow-up for Project 2, and preparation and submission of IRB regulatory-related materials to satisfy Continuing Review requirements (both Projects). After the completion of follow-up activities at Project 2 intervention site during the second quarter, we focused on developing the process of merging data from individual site databases; we then merged all de-identified intervention site data into one database. Finally, we have submitted a no-cost extension for both projects to allow for continuing participant enrollment in Project 1 and follow-up for both Projects. At many study-sites, lengthy initial regulatory review processes delayed the beginning of recruitment and as a result, participant enrollment has been lower than expected. A detailed summary of the progress for each project is detailed below.

Key Research Accomplishments

For the 4th year reporting period, here is a listing of all activities associated with SAFEMIL and SAFEVET.

Section I – SAFEMIL Progress
Safety Planning for Military (SAFE-MIL) - Walter Reed National Military Medical Center

1. Enrollment and Participant Follow-Up
As of September 24, 2013 (the end date for the current Annual Report), we have enrolled 93 participants in the SAFEMIL study (26 participants have been enrolled in the past year). We began conducting follow-up assessments with participants on September 29, 2011. As of September 24, 2013, we have successfully completed 63 one-month follow-up assessments and 52 six-month assessments. A total of 19 participants are active in the study.

2. Amendment Package Submitted
An amendment package was submitted to our Lead IRB site (WRNMMC) on October 31, 2012. The purpose of the amendment was to edit both the study protocol and the study consent form. Changes to the protocol included:
1. An updated list of qualified research personnel
2. The addition of a study site to our existing protocol
3. The addition of mailing to improve study retention rates
4. Minor adjustments to the assessment battery

The study consent form was also modified to:
1. Update the language in our consent form per recommendations from, the Certificate of Confidentiality Coordinators at NIMH to reflect the limits of the certificate of confidentially.
2. Make the language and study procedures described in our study documents more consistent with guidelines being recommended by the IRB at Walter Reed National Military Medical Center (WRNMMC), related to transporting study related documents.
3. Update the consent form to reflect exceptions to confidentiality.
4. Update the consent form to reflect a more accurate time frame for the completion of the study assessment sessions.
5. Provide example of the flyer which will be used to educate potential participants on the inpatient unit of WRNMMC and the Fort Belvoir Community Hospital.

All changes submitted in the amendment were also submitted and subsequently approved at the time of continuing review, detailed below.

3. Continuing Review
We submitted our continuing review report to WRNMMC IRB (our lead site) on November 5, 2012, one month prior to the expiration date of our previous continuing review approval from the WRNMMC IRB, which was December 14, 2012. The WRNMMC IRB formally met and reviewed our continuing review report on December 17, 2012. However, because this was three days after the expiration date of our previous study approval, the WRNMMC IRB required us to temporarily stop all study-related activities including recruitment as of December 14, 2012 until they approved our recently submitted continuing review. We resumed all study-related activities on February 11, 2013 after the WRNMMC IRB provided official approval for our study for the subsequent 12 months to expire on December 16, 2013.

4. New site specific IRB packages developed
At the request of the WRNMMC IRB, the study was required to create separate IRB packages with site specific study materials for a local site (WRNMMC) along with satellite sites (Fort Belvoir). The packages were submitted and approvals for these packages were obtained under a lead IRB package described above.

5. New Site Principal Investigators
Given the requirements for local site PIs to be credentialed provider at the site, the WRNMMC site PI was changed from Dr. Marjan Holloway to Dr. Geoffrey Grammer. Additionally, Dr. Jennifer Weaver was chosen as the Fort Belvoir site PI. These changes are reflected on the study protocol and study consent forms.

6. Data Cleaning
During the lapse in recruitment due to IRB approval delays in January 2013, Safemil team members conducted a self-audit of all files to ensure all files where complete and for ease of data entry into the study data bases.

7. Data Entry to the SAFEMIL Master Database with Double Data Entry Capacity
A comprehensive database was developed and finalized in the fourth quarter of FY2011. In September 2012 we began data entry into a master database with double data entry reconciliation capacity. Almost 100% (98.9%) of our data is currently entered into the database, 97.8% of our data has been double entered. Over half (51%) of the data entered has been confirmed accurate through additional verification with our paper research files.

8. Data and Safety Monitoring Board (DSMB)
A Data Safety Monitoring Board was convened on February 8th, 2013. The meeting resulted in modification to the monitoring for adverse events to include all adverse events rather than solely "serious adverse events" as required by the WRNMMC IRB.

9. Submission of Quarterly Reports
The Team continued to prepare and submit quarterly reports. The Final report for Year 3 was submitted by October 24th, 2012. The Quarterly Reports for year 4 were submitted for the following dates: January 15th, 2013 and April 15th, 2013th.
The Quarter 3 Report due July 15th, 2013, was waived due to a presentation provided by Dr. Marjan Holloway at the Suicide Prevention IPR.

10. Updated Safety Plan
Pocket Sized Safety plans were implemented into the study in the May 2013.

11. Staff Refresher Course
Students and Staff were provided with an updated SAFEMIL refresher course on October 1, 2012. This course allowed both students and affiliated staff an opportunity to refresh their knowledge of study related procedures and increase fidelity to the study protocol.

12. Data Sharing Agreements (DSA)
At the request of our IRB in 2011, we have written a DSA with the Armed Forces Health Surveillance Center (AFHSC). The DSA has been submitted and received for approval. After months of modifications we received a completed and approved DTM on July 22, 2013.

13. Ft. Belvoir Recruitment Site Update:
Fort Belvior was added as an approved additional site. Since the last annual report the team has accomplished many tasks enabling access to this additional site. These accomplishments include obtaining approval for the Site Specific Adendum, receiving an endorsement letter from the site, and chosing Dr. Jennifer Weaver as the site PI. Dr. Weaver's HIPPA & CITI Training as well as her CV have been completed, submitted, and approved by the WRNMMC, USUHS and Fort Belvoir IRBs. Additionally, the team has revised the study consent form to include information relevant to this site. However, due to a number of administrative delays (e.g., security

clearances for our staff members, ambiguities on credentialing of research staff) and the need to bring recruitment to an end on December 24, 2013 (based on our most recent no cost extension request), we no longer plan to utilize this site for recruitment purposes.

Section II – SAFEVET Progress
Safety Planning for Veterans (SAFEVET) – VA Emergency Departments

Regulatory Approvals: We obtained Continuing Review approvals from local IRBs at all study sites during Year 4 of the project. In addition, the Chesapeake IRB provided Continuing Review approval for the entire study in June 2013. Finally, all study sites obtained Continuing Review approval from the HRPO since the last Annual Report. Therefore, all sites continue to have approval from all IRBs and the HRPO.

Enrollment and Follow-up: Recruitment at all actively recruiting sites was ended on 8/24/2013. Follow-up assessments will continue at those sites with active participants. Please see below for current status at each site.

a. Bronx VAMC: The Bronx site ended recruitment activities on 8/24/2013. At that point, the site had enrolled 16 participants, 6 of whom have completed the 6-month follow-up assessment. There remain 2 participants who are active in the follow-up portion of the study.

b. Denver: The Denver site completed recruitment activities during Year 3 of the project. Seventy five participants were recruited at that site. During Year 4, follow-up activities were completed. Overall, 38 participants completed the 6-month follow-up assessment.

c. Long Beach VAMC: The Long Beach site ended recruitment activities on 8/24/2013. At that point, the site had enrolled 47 participants, 14 of whom have completed the 6-month follow-up assessment. There remain 4 participants who are active in the follow-up portion of the study.

d. Manhattan VAMC: The Manhattan site ended recruitment activities at the end of Year 3 of the project. Fifty three participants were recruited at that site. During Year 4, follow-up activities were completed. Overall, 12 participants completed the 6-month follow-up assessment.

e. Milwaukee VAMC: The Milwaukee site ended recruitment activities on 8/24/2013. At that point, the site had enrolled 64 participants, 28 of whom have completed the 6-month follow-up assessment. There remain 13 participants who are active in the follow-up portion of the study.

f. Philadelphia VAMC: The Philadelphia site ended recruitment activities at the end of Year 3 of the project. Sixty two participants were recruited at that site. During Year 4, follow-up activities were completed. Overall, 29 participants completed the 6-month follow-up assessment.

g. Portland VAMC: The Portland site ended recruitment activities during Year 3 of the project. Thirteen participants were recruited at that site. During Year 4, follow-up activities were completed. Overall, 4 participants completed the 6-month follow-up assessment.

h. San Diego VAMC: The San Diego site ended recruitment activities in December 2012. Two participants were recruited at that site. During Year 4, follow-up activities were completed. Overall, 1 participant completed the 6-month follow-up assessment.

Activities for Canandaigua VAMC Site:

The Center of Excellence at Canandaigua is the principal coordinating site for the SAFE VET clinical demonstration project, which is the basis for the VA-based portion of the project: A Brief Intervention to Reduce Suicide Risk in Military Service Members and Veterans. Grant-related activities for the period 9/25/2012 through 9/24/2013 included:

1. Participated in weekly PI conference calls.
2. Participated in monthly SAFE VET control site conference calls through completion of calls this year.
3. In conjunction with Philadelphia VAMC site, coordinated Adverse Event Data for SAFE VET intervention and control sites.
4. Worked with PI group to collect, maintain, and develop analysis plan for project data.
5. Worked with PI group to outline future manuscripts and publication/dissemination strategy.
6. Presented SAFE VET/SAFE MIL progress updates at VISN-2 COE Advisory and Executive Boards.
7. Worked to complete subject enrollment and data completion at study sites at Portland VAMC and control site at San Diego VAMC.
8. Managed IRB updates and continuing review: Syracuse VAMC.
9. Working with PI group, initiated two manuscripts describing SAFE VET/MIL Design and Methodology to be submitted for publication in third quarter of 2013.

Activities at Columbia University Site

1. Training and Supervision of Study Assessors
Training for all study assessors at the USUHS site of the SAFE-MIL Study (Project 1) continued in order to ensure adherence, fidelity and competency. One new rater was trained and credentialed at USUHS during the past year. Dr. Stanley took the lead in reviewing the assessor's work. As part of her training, the assessor was audio recorded completing an interview. This recording was evaluated for adherence and the assessor was given feedback.

2. Updated IRB Approvals and Renewals
During the reporting period, the Bronx VAMC and the Manhattan VA received continuing review approval at their local IRB and HRPO.

3. Continuing Rater Training and Evaluation
CUMC maintains responsibility for rater training and evaluation for SAFEVET (Project 2). Dr. Stanley gave verbal and written feedback to all assessors for the project following evaluation of rater training tapes. In addition, raters' meetings were organized and chaired by Dr. Stanley and occurred on an as needed basis. During these meetings, suicide-related events were discussed in order to bring their classifications to consensus. Dr. Stanley served as the liaison between the PI Steering Committee and the Raters Committee.

4. Data Collection
Data collection at the Manhattan VA began in September 2010 and ended in September 2012; 53 Veterans were enrolled. During the past year, 6 Veterans completed the 6-month follow-up at this site. Data collection at the Bronx VA began in February 2012 and ended in August 2013; 16 Veterans were enrolled. During the past year, 2 baseline assessments were completed and six 6-month assessments were completed.

5. Dissemination of study-related information
Columbia University has taken the lead on a manuscript that details the SAFEVET intervention with case examples. Substantial progress has been made on the manuscript this year. In addition, Columbia University

has taken the lead on a manuscript based on the key informant interviews. This manuscript is near ready for submission to a scientific journal.

Activities at the Denver VAMC Site

1. The Denver VA site received Continuing Review approval from their local IRB, Chesapeake IRB and HRPO. They have also received approvals for amendments that were submitted to remain in compliance with changing VA requirements. The Long Beach site continued collaborations with the Denver site in regards to regulatory requirements. The Long Beach site also received approval from their local IRB, Chesapeake IRB and HRPO.

2. The Denver site PI continued to participate in weekly control site and/or PI conference calls. The Denver site Study Coordinator and/or Assessor continued to participate in monthly phone calls to facilitate communication and consistency across sites.

3. Regarding assessment, the Denver site hired a new assessor and worked to get her trained on the assessment battery. She was approved as an assessor and assisted in the completion of assessments of Denver participants and Long Beach participants.

4. During year 4, the Long Beach site recruited 14 new participants for a project total of 47. During year 4, the assessors at the Denver site completed the 6 month follow up assessment for 14 participants at the Long Beach site for a project total of 14 completions.

5. As of the end of year 3, Denver had recruited all 75 participants for the study. As such, Denver continued to conduct 1 month, 3 month and 6 month follow-up assessments during year 4. The last participant enrolled at the Denver site was lost to follow up on 3/27/13. As of this date, follow up assessments for Denver participants were complete. A total of 14 participants completed the study in year 4, for a project total of 38 completions.

6. Throughout year 4, the Denver site continued to collaborate with the Long Beach site behind the VA firewall to facilitate the secure sharing of data

Activities at the Philadelphia VAMC Site

1. Since the beginning of the study, the Philadelphia VAMC site enrolled 62 participants and 29 have completed the study. The Milwaukee VAMC site enrolled 64 participants and 28 have completed the study.

2. Study assessors at the Philadelphia VAMC site participated in monthly assessor calls with the other study sites.

3. IRB approval for our continuing review was received on February 5, 2013. The Philadelphia VAMC site assisted all sites with completing continuing review and amendment submissions and coordinated sites' continuing review submissions to Chesapeake IRB and the HRPO. We advised sites on local SAE reporting requirements, disseminated local SAE reports to all MOMRP sites, provided guidance to all sites on reporting of external SAEs, and coordinated the submission of SAE reports to Chesapeake IRB and the HRPO as required. We tracked all sites' current IRB due dates and status of sites' continuing reviews and amendment submissions.

3. The Philadelphia VAMC site provided guidance and quality control to all assessment sites regarding the assessment database. We helped SAFEMIL staff troubleshoot data entry errors and provided guidance on

cleaning data and double data entry.

4. The Philadelphia VAMC site tracked all sites' screening and enrollment, participant follow-up, and adverse events and we created reports which were presented to project PIs on a weekly basis.

5. The Philadelphia VAMC developed the process of merging data from individual site databases. We obtained de-identified data from the 4 Intervention sites and merged the data into one database.

Reportable Outcomes

- **Peer Reviewed Manuscripts**

United States Air Force Medical Operations Agency. (2013). Air Force guide for suicide risk assessment, management, and treatment. San Antonio, Texas. (Prepared with funding provided by the United States Air Force to Dr. Ghahramanlou-Holloway for project titled, "Enhancing United States Air Force Suicide Prevention Efforts.")

- **Presentations**

Stanley, B., Matweychuk, W., Carreno Ponce, J. T., Ghahramanlou-Holloway, M., & Brown, G. (2013, April). The Safety Plan Intervention: An Overview. In: Overcoming Clinical Challenges in the Delivery of Safety Planning Intervention for Military Personnel and Veterans. Workshop presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.

Stanley, B., Matweychuk, W., Carreno Ponce, J. T., Ghahramanlou-Holloway, M., & Brown, G. (2013, April). Safety Planning Intervention: Challenges and Obstacles to Implementation. In: Overcoming Clinical Challenges in the Delivery of Safety Planning Intervention for Military Personnel and Veterans. Workshop presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.

Brown, G. K., Green, K., & Ghahramanlou-Holloway, M. (2013, April). Cognitive Therapy for the Prevention of Suicide Among Military Personnel and Veterans: Ongoing Research and Clinical Recommendations. Workshop presented at the Annual Meeting of the American Association of Suicidology, Austin, TX.

Ghahramanlou-Holloway, M., Brown, G. K., Brenner, L., Currier, G., & Knox, K. (2013, May). Brief Intervention to Reduce Suicide Risk in Military Service Members and Veterans. Suicide IPR Annual Meeting, Fort Detrick, MD.

Carreno-Ponce, J. T., & Ghahramanlou-Holloway, M. (2013, August). Current intervention evaluations underway: The "SafeMil" and "PACT" randomized controlled trials at WRNMMC. Breakout session presented at the Military Health System Research Symposium, Ft. Lauderdale, FL.

Conclusion

For SAFEMIL, the fourth year has been focused on participant recruitment and follow-up, writing and submitting amendments to the study, adding a second recruitment site, refining the study and recruitment procedures, and personnel transition. As of September 24, 2013, we have enrolled 93 participants into the SAFEMIL study, 52 of these participants have completed the 6-month assessment and 19 remain active in the study. Of these enrolled, 26 have been enrolled since the time of the last annual report. Please see Appendix E for Project 1 CONSORT diagram.

Regarding the SAFEVET study, the fourth year focused on obtaining appropriate IRB continuing review approvals at all sites, coordinating activities between Assessment sites and their paired Control sites, and on patient recruitment at Control sites and follow-up at all sites. At the end of Year 4, all sites have ended recruitment activities. As of September 24, 2013, 332 participants had been enrolled into the SAFEVET study across all eight sites, 132 have completed the 6-month assessment and 19 participants remain active in the study. In the past year, 48 participants have been enrolled and 67 have completed the 6-month assessment.

This study represents the only combined efficacy and effectiveness trial addressing the needs of military personnel and veterans following a suicidal crisis. Given the magnitude of the public health problem presented by suicide-related ideation and behaviors in the military, there is a significant need for empirically supported treatments that directly address the needs of this at high-risk individuals.

References

None.

Appendices

Appendix A: IRB Related Progress for SAFEVET and SAFEMIL Projects

Appendix B: SAFEVET Enrollment Report and Adverse Event Log

Appendix C: SAFEMIL Enrollment Report and Adverse Event Log

Appendix D: SAFEVET and SAFEMIL Participants Lost to Follow-up

Appendix E: SAFEMIL CONSORT Diagram, Since Last Annual Report

Appendix F: SAFEMIL Baseline Demographic Data

Appendix G: SAFEMIL Baseline Suicide Attempt Data

APPENDIX B
SAFEVET Enrollment Report and Adverse Event Log (As of September 24, 2013)

IRB	Site #1 Bronx VAMC CONTROL	Site #2 Canandaigua VAMC ASSESSMENT SITE[1]	Site #3 San Diego VAMC CONTROL	Site #4 Denver VAMC SAFEVET	Site #5 Long Beach VAMC CONTROL
Site PI	Leo Sher	Glenn Currier Kerry Knox	Kathleen Kim	Lisa Brenner	Lawrence Albers
VA IRB	Initial Approval 12/2/10 CR Approved: 10/4/12	Syracuse IRB Initial Approval 1/3/11 CR Approved: 10/29/12	Initial Approval 3/3/11 CR Approved: 2/14/13	Initial Approval 5/7/10 CR Approved: 2/5/13	Initial Approval 6/9/11 CR Approved: 2/14/13
PI Institutional IRB	NA	NA	NA	NA	NA
Chesapeake IRB	Initial Approval 5/25/11	Initial Approval 4/5/11	Initial Approval 7/6/2011	Initial Approval 9/09/2010	Initial Approval 8/31/11
HRPO	Initial Approval 6/21/11 HRPO A-15768.h	Initial Approval 5/25/11 HRPO A-15768.f	Initial Approval 6/25/12 HRPO A-15768.i	Initial Approval 9/14/10 HRPO A-15768.a	Initial Approval 9/20/11 HRPO A-15768.j
Other IRB	NA	NA	NA	NA	NA
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk
SAMPLE SIZE	N = 75 at BVAMC	N = 75 at CVAMC	N = 75 at SDVAMC	N = 75 at DVAMC	N = 75 at LBVAMC

[1] Assessment Center for San Diego and Portland VAMCs

IRB	Site #6 Manhattan VAMC SAFEVET	Site #7 Milwaukee VAMC CONTROL	Site #8 Philadelphia VAMC SAFEVET	Site #9 Portland VAMC SAFEVET	Site #10 WRAMC SAFEMIL
Site PI	Christie Jackson	Bert Berger	Gregory Brown	Lauren Denneson	Marjan Holloway
VA IRB	Initial Approval 5/3/10 CR Approved 2/4/13	Initial Approval 2/15/11 CR Approved 2/4/13	Initial Approval 5/12/10 CR Approved: 1/26/13	Initial Approval 11/3/210 CR Approved: 6/4/13	NA
PI Institutional IRB	NA	NA	NA	NA	USUHS (SAFEMIL ONLY) Initial Approval 12/22/11
Chesapeake IRB	Initial Approval 6/17/10	Initial Approval 4/5/11	Initial Approval 8/09/10	Initial Approval 1/31/11	NA
HRPO	Initial Approval 9/24/10 HRPO A-15768.b	Initial Approval 5/25/11 HRPO A-15768.g	Initial Approval 9/02/10 HRPO A-15768.c	Initial Approval 2/28/11 HRPO A-15768.d	Initial Approval 2/17/12 HRPO A-15768.e
Other IRB	NA	NA	NA	NA	WRNMMC Initial Approval 12/22/11 CR Approved 2/11/13
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	Greater than Minimal Risk
SAMPLE SIZE	N = 75	N = 75	N = 75	N = 75	N = 186

CR = Continuing Review; CIC = Clinical Investigations Committee; HRPO = Human Research Protections Office; HUC = Human Use Committee; USUHS = Uniformed Services University of the Health Sciences; VAMC = Veterans Affairs Medical Center; WRAMC = Walter Reed Army Medical Center

APPENDIX B
SAFEVET Enrollment Report and Adverse Event Log (As of September 24, 2013)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Enrolled	Active	Completed Baseline Assessment	Completed 1-mo follow-up	Completed 3-month follow-up	Completed Study	Lost to Follow-up	# AEs
Total (all sites):	**484**	**100**	**52**	**332**	**19**	**238**	**185**	**153**	**132**	**181**	**11**
Bronx	22	3	3	16	2	11	7	4	6	8	0
Denver	87	9	3	75	0	59	47	41	38	37	2
Long Beach	71	10	14	47	4	26	22	20	14	29	3
Manhattan	95	27	15	53	0	31	16	16	12	41	2
Milwaukee	95	22	9	64	13	56	47	36	28	23	2
Philadelphia	92	25	5	62	0	45	39	31	29	33	1
Portland	20	4	3	13	0	8	6	4	4	9	1
San Diego	2	0	0	2	0	2	1	1	1	1	0

SAFEVET Adverse Events Log (As of September 24, 2013)

Site	Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected	Description
Manhattan	2/17/11	2/18/11	2/25/11	No	Yes	Suicide Attempt
Philadelphia	7/13/11	7/29/11	7/29/11	No	No	Hit by Train Resulting in Death
Denver	8/2/11	8/5/11	8/8/11	No	Yes	Suicide Attempt Resulting in Death
Portland	4/26/12	5/24/12	5/29/12	No	Yes	Suicide Attempt
Milwaukee	5/15/12	5/15/12	5/21/12	No	No	Suicidal Ideation/Homicidal Ideation
Manhattan	5/10/12	5/24/12	6/1/12	No	Yes	Suicide Attempt
Long Beach	6/27/12	6/27/12	7/3/12	No	Yes	Suicide Ideation leading to inpatient hospitalization
Long Beach	10/10/12	10/23/12	10/29/12	No	Yes	Lethargy and hypersomnolence leading to involuntary hospitalization
Long Beach	12/29/2012	1/3/2013	1/3/2013	No	Yes	Substance induced psychosis leading to inpatient hospitalization
Milwaukee	2/4/2013	2/5/2013	2/6/2013	No	Yes	Suicide Attempt
Denver	12/18/2012	2/27/2013	3/4/2013	No	Yes	Increased depression and suicidal ideation leading to inpatient hospitalization

APPENDIX C

SAFEMIL Enrollment Report and Adverse Event Log (As of September 24, 2013)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Eligible but not Enrolled – Other Reasons	Enrolled	Active	Completed Baseline Assessment	Completed Discharge Assessment	Completed 1-month follow-up	Completed 6-month follow-up	Lost to Follow-up	# AEs
SAFEMIL	296	85	49	69	93	19	93	85	63	52	22	4

SAFEMIL Adverse Events Log (As of September 24, 2013)

Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected/ Unexpected	Description
10/4/2011	10/5/2011	10/5/2011	No	Yes	Suicide Ideation leading to involuntary hospitalization
10/1/2011	11/2/2011	11/2/2011	No	No	Participant in federal custody
12/3/2011	12/4/2011	12/6/2011	No	Yes	Admitted to inpatient unit for possible suicide ideation, cutting behaviors, and high blood alcohol content.
10/11/2011	11/8/2011	11/9/2011	No	Yes	Depression leading to voluntary psychiatric hospitalization

APPENDIX D

SAFEVET and SAFEMIL Participants Lost to Follow-up (As of September 24, 2013)

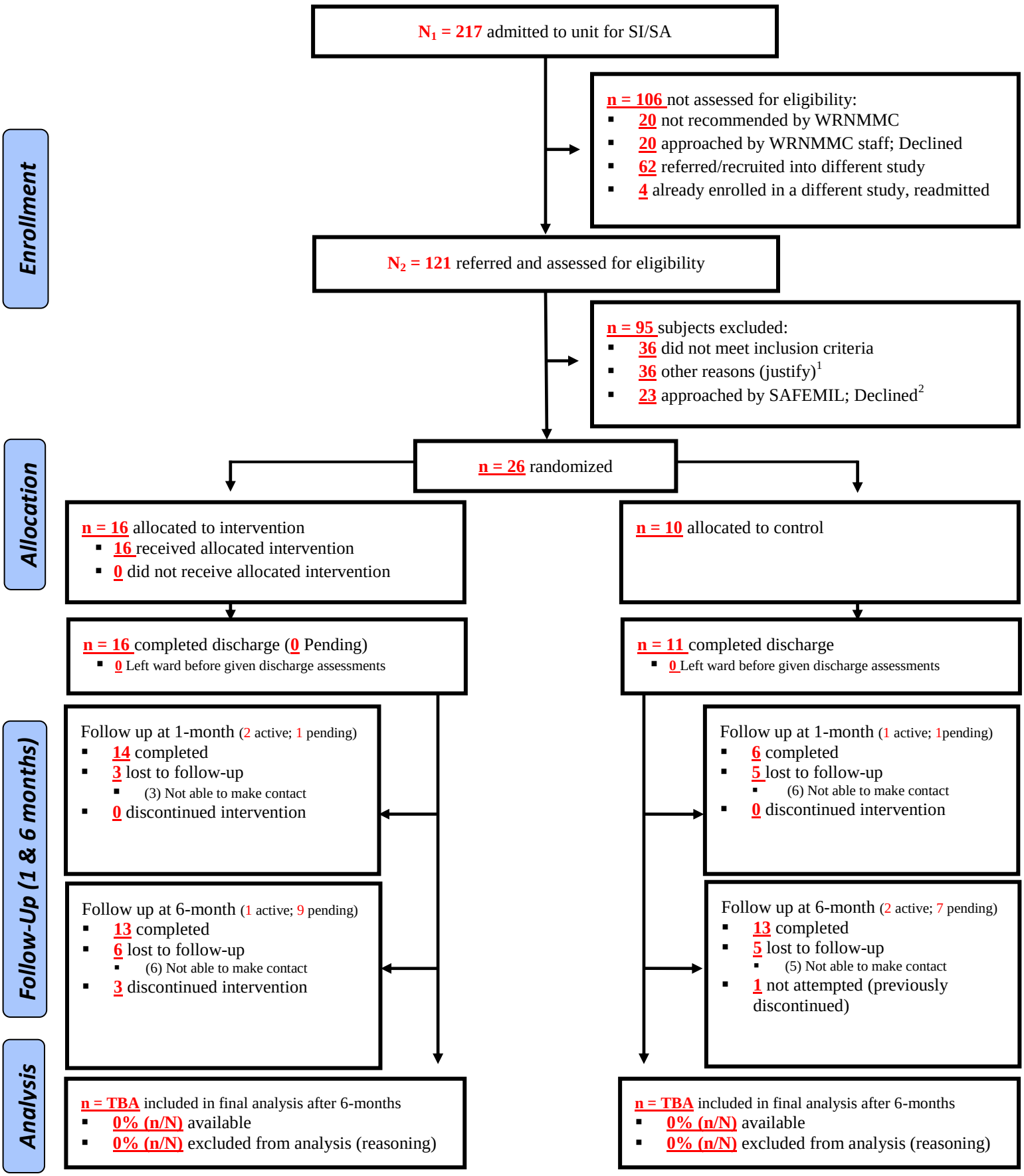
SAFEVET Reasons for Participants Lost to Follow-up

181	Total # of subjects lost to follow-up
78	Withdrawn because did not complete baseline assessment
66	Did not complete 6-month follow-up assessment
14	Subjects withdrew because no longer interested in participating or gave no reason
6	Subjects withdrew because no longer comfortable with study
5	Subjects withdrew because too busy to complete assessments
3	Did not meet entry criteria
2	Subjects deceased
2	Feels that the assessments are too long
2	Claims that the assessment questions are not pertinent to him
1	"Dissatisfied with the VA"
1	"Not helpful bringing up past"
1	"Feeling better"

SAFEMIL Reasons for Participants Lost to Follow-up (SAFEMIL)

22	Total # of subjects lost to follow-up
15	Not able to make contact
5	Discontinued intervention
1	Withdrew because no longer wants to be in study
1	Withdrawn because participant was imprisoned

Appendix E
SAFEMIL CONSORT Diagram (Since Last Annual Report)
September 25, 2012 – September 24, 2013



Appendix F

SAFEMIL Baseline Demographic Data

Table 1. Sample Demographics for SAFEMIL (N = 91)*	**Treatment (n = 48)**	**Control (n = 43)**
Age, mean (SD), years	28.6 (8.9)	31.1 (9.6)
Gender		
Male	35 (72.9)	27 (62.8)
Female	13 (27.1)	16 (37.2)
Race/Ethnicity		
Black/African-American	5 (10.4)	3 (7.0)
Hispanic/Latino	4 (8.3)	3 (7.0)
White	34 (70.8)	29 (67.4)
Multi-racial	5 (10.4)	6 (14.0)
Other	0	2 (4.7)
Education		
High school diploma/equivalent	13 (27.1)	7 (16.3)
Some college	20 (41.7)	19 (44.2)
Associate's degree	4 (8.3)	6 (14.0)
Bachelor's degree	8 (16.7)	6 (14.0)
Graduate degree	3 (6.2)	5 (11.6)
Marital Status		
Single	22 (45.8)	13 (30.2)
Cohabitating	3 (6.2)	1 (2.3)
Married	13 (27.1)	16 (37.3)
Separated/Divorced/Widowed	9 (18.7)	12 (27.9)
No response	1 (2.1)	1 (2.3)
Military Deployment		
Yes	29 (60.4)	25 (58.1)
No	19 (39.6)	17 (39.5)
No response	0	1 (2.3)
Military Combat		
Yes	13 (27.1)	11 (25.6)
No	35 (72.9)	31 (72.1)
No response	0	1 (2.3)

* Data presented as No. (%), except as noted

Table 2: Suicide Attempt Status at Time of Hospitalization

	Treatment (n = 48)	**Control (n = 43)**
Suicide Attempts		
Yes	25 (52.1)	23 (53.5)
No	23 (47.9)	20 (46.5)

Table 3: Number of Prior Suicide Attempts at Baseline

	Treatment (n = 48)	**Control (n = 43)**
No. of Suicide Attempts		
0	23 (47.9)	20 (46.5)
1	18 (37.5)	16 (37.2)
2	6 (12.5)	5 (11.6)
3	1 (2.1)	1 (2.3)
4	0	1 (2.3)